

I. Remarks

A. Applicants Have an Earlier Date of Construction and Reduction to Practice

Claims 11-17, 19 – 21, 27 – 29 and 31 presently stand rejected under 35 U.S.C. §102(e) as being anticipated by Miller *et al.* (US Application Serial No. 10/799,999, published as US Patent Application Publication No. 2004/0180919). Claims 18 and 35 – 38 are presently rejected under 35 U.S.C. §103(a) as being obvious based on the teaching of Miller *et al.* For the reasons set forth below and in the accompanying Supplemental 1.131 Declaration of Dr. Baumann, Applicants respectfully traverse and request reconsideration and withdrawal of these rejections.

On Page 13 of the February 8, 2008 Non-Final Office Action, reference is made to MPEP Section 715 for the proposition that a declaration under 37 CFR §1.131 is not appropriate where the cited §102(e) prior art is a patent application publication that claims the same patentable invention. Later on Page 13 of the February 8, 2008 Non-Final Office Action, the conclusion is reached “that one of ordinary skill in the art would interpret the claims of Miller *et al.* as including imiquimod as a specific embodiment, thereby claiming the same invention as the instant application.”

In response, Applicants note that in a Final Office Action mailed on May 14, 2008, all claims pending in US Application Serial No. 10/799,999 were rejected, *inter alia*, as being obvious under 35 U.S.C. §103(a). Accordingly, at the present time, neither the invention claimed in the present application nor in US Application Serial No. 10/799,999 have been found to be patentable.

Applicants respectfully submit that pursuant to MPEP Section 2305, a declaration under 37 CFR §1.131 is therefore appropriate. As explained in Example I of MPEP Section 2305, “if a published application contains claims to the same invention, but the claims in the published application are not in condition for allowance, then no interference is yet possible.” The Example continues, stating, “Since the claims in the published application might never be allowed in their present form, it is not appropriate to proceed as though an interference would be inevitable. Consequently, an affidavit under 37 CFR 1.131 may be submitted.” (emphasis added.)

In Dr. Baumann's Declaration submitted on November 26, 2007, she explained that certain notes and medical records were not attached to that declaration because patient medical information is protected under federal law and university policy. Page 13 of the February 8, 2008 Non-Final Office Action responds to this privacy concern by noting that in cases such as the instant application, it is appropriate to include copies of the relevant records with all identifying information such as names blacked out to preserve the patients' privacy. This is done in Dr. Baumann's Supplemental 1.131 Declaration submitted with this Response.

In the carry-over paragraph between Pages 12 and 13 of the February 8, 2008 Non-Final Office Action, reference is made to the type of evidence that may be shown to establish reduction to practice prior to the effective date of the cited prior art reference, or conception of the claimed invention prior to the effective date of the cited reference coupled with due diligence from prior to date of the cited reference to subsequent reduction to practice or to the filing of the application. In Dr. Baumann's 1.131 Declaration, Applicants respectfully submit that these showings are made.

Dr. Baumann explains the circumstances of conception and how the claimed invention was reduced to practice both through the treatment of patients with normal photo-damaged skin for fine lines and clinical wrinkles by topical application of Aldara and by the filing of the instant patent application. See Supplemental 1.131 Declaration, ¶¶ 2 – 3.

Dr. Baumann details the steps taken to secure the approval of the University of Miami's Institutional Review Board (the "IRB") in order to proceed with a formal clinical study. These steps included preparing, revising and obtaining required approvals from University attorneys and the IRB (*i.e.*, clinical trial protocol, patient instructions, case report forms, informed consent forms and patient recruitment advertisements). See Supplemental 1.131 Declaration, ¶¶ 6 -7, 9 – 12.

Moreover, as Dr. Baumann explains, since Applicant's study of Aldara for photoaging was self-supported by an academic medicine department – the Cosmetic Center of the University of Miami Department of Dermatology – and not by outside grants (*i.e.*, from industry or government), Applicants needed to secure funding, sufficient supplies of

Aldara, and necessary instrumental equipment in order to move forward with the clinical trial. See Supplemental 1.131 Declaration, ¶ 13.

In addition, prior to and throughout this IRB approval process, Dr. Baumann continued to see and treat patients for photoaging as claimed in the instant application. See Supplemental 1.131 Declaration, ¶ 8.

B. Supplemental IDS

In the Supplemental Information Disclosure Statement submitted herewith, Applicants request that consideration be given to US Patent No. 6,335,023 ("Yu") published on January 1, 2002. The Yu reference is directed to topical compositions comprising aldonic acid and methods for treating or preventing cosmetic conditions or dermatological disorders with compositions containing aldonic acid. Imiquimod (Aldara) is included in a laundry list of 164 ingredients broadly described as "cosmetic, pharmaceutical, or other topical agents" that are disclosed as possibly being added to compositions containing aldonic acid. Applicants respectfully submit that a laundry list disclosure of this type would not teach, suggest, or motivate a person having ordinary skill in the art to use of imiquimod for the uses claimed in the instant application nor would such a laundry list disclosure give a reasonable expectation that using imiquimod would result in a reduction in the appearance of fine lines and clinical wrinkles in normal photo-damaged skin. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a "laundry list" disclosure would not reasonably lead those skilled in the art to a particular species in the disclosed list.)

Conclusion

For the above reasons, reconsideration and withdrawal of the rejections are respectfully requested. If the Examiner believes that an interview will expedite review, please contact undersigned counsel.

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Respectfully submitted,
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